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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,139	11/20/2001	Mark Thiede	640100-420	9767

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,139	Applicant(s) THIEDE ET AL.	
	Examiner Joseph T. Voitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 9-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a 371 national stage filing of PCT/US99/26927, filed November 12, 1999, which claims benefit to provisional application 60/108,357, filed November 13, 1998.

Claims 1-27 are pending.

Election/Restriction

Applicant's election of group II, claims 6-8, with traverse is acknowledged. It was noted that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-27 are pending. Claims 1-5, 9-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 6-8 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims drawn to nonelected invention elected with traverse (see paper 3, page 1). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a well asserted utility or a well established utility.

The specification teaches and provides evidence that mesenchymal stem cells can be transplanted *in utero* and that the implanted cells will distribute throughout the fetus, in some cases differentiating into cell types of organ in which they implanted. Based on the observed properties of the mesenchymal stem cells the specification proposes four potential clinical applications of: “1) large scale tissue engineering particularly for repair of musculoskeletal injury; 2) cellular therapy for diseases of mesenchymal origin such as muscular dystrophy, osteoporosis, osteogenesis imperfecta, and collagen disorders; 3) bone marrow conditioning to facilitate engraftment of autologous or allogeneic hematopoietic stem cells; and 4) gene therapy.” (page 25). Further, the specification continues to speculate that “[P]renatal MSC transplantation may provide a "reservoir" of normal stem cells to replace defective cells as they become damaged in degenerative diseases with progressive cellular and organ damage.” (page 25). The basis of the rejection focuses on the fact that while the specification reduces to practice the *in utero* transplantation of mesenchymal stem cells, and that the cells appear to distribute throughout the organs in the engrafted animal, the specification fails to provide a nexus wherein this phenomena will result in the proposed utilities.

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With respect to tissue engineering the specification fails to provide any specific guidance on how a chimeric organ would or could be used in any context. Further, while it is acknowledged that mesenchymal cells implanted *in utero* will distribute into various tissues and organs in the fetus and be detectable in the resulting animal, the process by which this occurs is random and not subject any specific manipulation which would be consistent with generating a engineered tissue for further use. Moreover, with respect to using the engineered tissue for repair of musculoskeletal injury or in treating diseases of mesenchymal origin, there is no objective evidence that the implanted cells will obviate any specific damage that is present or will counter act any potential damage in diseases such as muscular dystrophy, osteoporosis, osteogenesis imperfecta or collagen disorders. For example, if an altered form of collagen is expressed by the cells of the host animal, it is unclear how providing a second source of collagen would alleviate any of the consequences of the altered collagen. The altered form of collagen would be present and the consequences of its presence would still be maintained resulting in the same condition associated with a given disorder. With respect to conditioning a tissue for engraftment, it may be that any resulting tissue from an animal implanted with mesenchymal stem cells could possess antigens of the animal into which it would be transplanted, however this affect would not counter all the foreign antigens associated with the donor. Thus, while the tissue may contain cells that would not be recognized as foreign relative to the animal in which it is to be delivered, the potential for rejection is not counteracted relative to the foreign antigens that still exist within that tissue. Finally, with respect to the use of the method for gene therapy, it is unclear how the present method would be used to affect gene therapy. Currently, the art recognizes multiple limitations to affecting gene therapy including

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problems with gene delivery and gene expression, and it is unclear how the present method would be sued specifically to ameliorate any of the art recognized problems. Moreover, even in methods which appear to be affective in treating certain symptoms of a given disease, there is no guidance on how these gene therapy methods should be adapted with the methods as claimed.

It should be noted that the basis of the rejection does not focus on the clinical applicability of the claimed method, rather the fundamental applications as proposed. As reasoned above, each of the proposed utilities do not represent methodology common in the art and lack any specific real world context for use. It may be argued that the claimed method meets the utility requirement in that “an invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications” (Carl Zeus Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991)). However, in the instant case, the claims lack utility not because they are incomplete, and not because they do not set forth the best or only way to accomplish a result, and not because they are not unique, but because they do not have either a well-established utility or a specific and substantial asserted utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for

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the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The specification provides insufficient guidance and teaching on how to accomplish the proposed utilities specifically set forth. The high degree of unpredictability associated with the proposed utilities of the claimed method underscores the need to provide teachings in the specification that would provide the artisan with specific guidance or regimens for use of an engineered tissue that would result from the method or that achieve for example a therapeutic benefit in gene therapy methods. However, the specification does not provide such guidance. Without such guidance in the specification and the lack of correlative working examples, the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

The instant invention, as claimed, falls under the “germ of an idea” concept defined by the CAFC. The court has stated that “patent protection is granted in return for an enabling disclosure, not for vague intimations of general ideas that may or may be workable”. The court continues to say that “tossing out the mere germ of an idea does not constitute an enabling disclosure” and that “the specification, not knowledge in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”. (See *Genentech inc v. Novo Nordisk A/S* 42 USPQ2d 1001, at 1005). The claimed methods of transfer constitute such a “germ of an idea”.

In view of the of the lack of guidance, working examples, breadth of the claims, skill in the art and state of the art at the time of the claimed invention, it would require undue experimentation by one of skill to practice the invention as claimed.

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Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732. After January 12, 2004, the Examiner's telephone number will be (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. After January 12, 2004, Deborah Reynolds telephone number will be (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141. After January 14, 2004, Dianiece Jacobs telephone number will be (571)272-0532.

Joseph T. Woitach


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